

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

**LIFE TECHNOLOGIES CORPORATION,
and APPLIED BIOSYSTEMS, LLC,**

Plaintiffs,

v.

**BIOSEARCH TECHNOLOGIES, INC.,
BIO-SYNTHESIS, INC., EUROFINS
MWG OPERON INC., and THE
MIDLAND CERTIFIED REAGENT
COMPANY, INC.,**

Defendants.

**CIVIL ACTION NO. 2:09-CV-00283
TJW-CE**

BIOSEARCH TECHNOLOGIES, INC.'S ANSWER AND COUNTERCLAIMS

ANSWER

Defendant Biosearch Technologies, Inc. ("Biosearch"), by and through its undersigned counsel, hereby answers the First Amended Complaint for Damages and Injunctive Relief for Patent Infringement ("FAC") of Plaintiffs Life Technologies Corporation and Applied Biosystems, LLC ("Plaintiffs") as follows:

Biosearch denies each and every allegation contained in Plaintiffs' FAC, except as specifically admitted or explained herein. To the extent that the headings or any other non-numbered statements in the FAC contain any allegations, Biosearch denies each and every such allegation.

In response to the paragraph on page 1 of the FAC, no answer is required.

JURISDICTION AND VENUE

1. Biosearch admits that the action brought by Plaintiffs purports to be an action arising under the patent laws of the United States. Biosearch admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338(a). Except as expressly admitted herein, Biosearch denies the remaining allegations of paragraph 1.

2. Biosearch admits, without admitting to the validity of Plaintiffs' infringement claims, that it is subject to personal jurisdiction in this judicial district and division. Except as expressly admitted herein, Biosearch denies the remaining allegations of paragraph 2 to the extent they pertain to Biosearch. To the extent these allegations pertain to another Defendant, Biosearch is without knowledge or information sufficient to form a belief as to the allegations and, on that basis, denies these allegations.

3. Biosearch admits, without admitting to the validity of Plaintiffs' infringement claims, that venue may be proper as to Biosearch in this judicial district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b). Except as expressly admitted herein, Biosearch denies the remaining allegations of paragraph 3 to the extent they pertain to Biosearch. To the extent these allegations pertain to another Defendant, Biosearch is without knowledge or information sufficient to form a belief as to the allegations and, on that basis, denies these allegations.

PARTIES

4. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 4 and, on that basis, denies said allegations.

5. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 5 and, on that basis, denies said allegations.

6. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 6 and, on that basis, denies said allegations.

7. Biosearch admits that the face of U.S. Patent No. 5,538,848 ("the '848 patent") shows it is entitled "Method for Detecting Nucleic Acid Amplification Using Self-Quenching Fluorescence Probe." Biosearch is without knowledge or information sufficient to form a belief

as to the remainder of the allegations contained in paragraph 7 and, on that basis, denies said allegations.

8. Biosearch admits that the face of U.S. Patent No. 5,723,591 (“the ‘591 patent”) shows it is entitled “Self-Quenching Fluorescence Probe.” Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 8 and, on that basis, denies said allegations.

9. Biosearch admits that the face of U.S. Patent No. 5,876,930 (“the ‘930 patent”) shows it is entitled “Hybridization Assay Using Self-Quenching Fluorescence Probe.” Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 9 and, on that basis, denies said allegations.

10. Biosearch admits that the face of U.S. Patent No. 6,030,787 (“the ‘787 patent”) shows it is entitled “Hybridization Assay Using Self-Quenching Fluorescence Probe.” Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 10 and, on that basis, denies said allegations.

11. Biosearch admits that the face of U.S. Patent No. 6,258,569 (“the ‘569 patent”) shows it is entitled “Hybridization Assay Using Self-Quenching Fluorescence Probe.” Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 11 and, on that basis, denies said allegations.

12. Biosearch admits the allegations in paragraph 12 of the FAC.

13. In response to paragraph 13, Biosearch admits that it manufactures, offers for sale and sells, modified oligonucleotides for biotechnology research purposes, such as in quantitative polymerase chain reaction (“qPCR”) assays.

14. In response to paragraph 14, Biosearch admits that it manufactures, offers for sale and sells probes incorporating customer specifications. The specifications may, but not necessarily, include a quencher and fluorophore reporter covalently linked to the 3' or 5' ends of an oligonucleotide typically 20 to 30 bases long. Except as expressly admitted herein, Biosearch denies the remaining allegations of paragraph 14.

15. In response to paragraph 15, Biosearch admits that it obtains revenue, at least in part, from fees charged for the manufacture and sale of dual-labeled probes incorporating a quencher and fluorophore reporter covalently linked to the 3' or 5' ends of an oligonucleotide. Except as expressly admitted herein, Biosearch denies the remaining allegations of paragraph 15.

16. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 16 and, on that basis, denies said allegations.

17. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 17 and, on that basis, denies said allegations.

18. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 18 and, on that basis, denies said allegations.

19. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 19 and, on that basis, denies said allegations.

20. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 20 and, on that basis, denies said allegations.

21. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 21 and, on that basis, denies said allegations.

22. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 22 and, on that basis, denies said allegations.

23. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 23 and, on that basis, denies said allegations.

24. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 24 and, on that basis, denies said allegations.

25. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 25 and, on that basis, denies said allegations.

26. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 26 and, on that basis, denies said allegations.

27. Biosearch is without knowledge or information sufficient to form a belief as to the

allegations contained in paragraph 27 and, on that basis, denies said allegations.

FIRST CLAIM FOR RELIEF

INFRINGEMENT OF UNITED STATES PATENT NO. 5,538,848

28. In response to paragraph 28 of the FAC, Biosearch realleges and incorporates by reference the answers stated in paragraphs 1-27 above.

29. Biosearch admits that the face of the '848 patent indicates it issued on July 23, 1996, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit A to the FAC. Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 29 and, on that basis, denies said allegations.

30. Biosearch denies each and every allegation of paragraph 30.

31. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 31 and, on that basis, denies said allegations.

32. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 32 and, on that basis, denies said allegations.

33. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 33 and, on that basis, denies said allegations.

34. Biosearch denies each and every allegation of paragraph 34.

35. Biosearch denies the allegations contained in paragraph 35 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 35 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

36. Biosearch denies the allegations contained in paragraph 36 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 36 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

SECOND CLAIM FOR RELIEF

INFRINGEMENT OF UNITED STATES PATENT NO. 5,723,591

37. In response to paragraph 37 of the FAC, Biosearch realleges and incorporates by reference the answers stated in paragraphs 1-36 above.

38. Biosearch admits that the face of the '591 patent indicates it issued on March 3, 1998, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit B to the FAC. Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 38 and, on that basis, denies said allegations.

39. Biosearch denies each and every allegation of paragraph 39.

40. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 40 and, on that basis, denies said allegations.

41. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 41 and, on that basis, denies said allegations.

42. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 42 and, on that basis, denies said allegations.

43. Biosearch denies each and every allegation of paragraph 43.

44. Biosearch denies the allegations contained in paragraph 44 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 44 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

45. Biosearch denies the allegations contained in paragraph 45 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 45 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

THIRD CLAIM FOR RELIEF

INFRINGEMENT OF UNITED STATES PATENT NO. 5,876,930

46. In response to paragraph 46 of the FAC, Biosearch realleges and incorporates by reference the answers stated in paragraphs 1-45 above.

47. Biosearch admits that the face of the '930 patent indicates it issued on March 2, 1999, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit C to the FAC. Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 47 and, on that basis, denies said allegations.

48. Biosearch denies each and every allegation of paragraph 48.

49. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 49 and, on that basis, denies said allegations.

50. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 50 and, on that basis, denies said allegations.

51. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 51 and, on that basis, denies said allegations.

52. Biosearch denies each and every allegation of paragraph 52.

53. Biosearch denies the allegations contained in paragraph 53 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 53 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

54. Biosearch denies the allegations contained in paragraph 54 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 54 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

FOURTH CLAIM FOR RELIEF

INFRINGEMENT OF UNITED STATES PATENT NO. 6,030,787

55. In response to paragraph 55 of the FAC, Biosearch realleges and incorporates by reference the answers stated in paragraphs 1-54 above.

56. Biosearch admits that the face of the '787 patent indicates it issued on February 29, 2000, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit D to the FAC. Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 56 and, on that basis, denies said allegations.

57. Biosearch denies each and every allegation of paragraph 57.

58. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 58 and, on that basis, denies said allegations.

59. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 59 and, on that basis, denies said allegations.

60. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 60 and, on that basis, denies said allegations.

61. Biosearch denies each and every allegation of paragraph 61.

62. Biosearch denies the allegations contained in paragraph 62 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 62 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

63. Biosearch denies the allegations contained in paragraph 63 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 63 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

FIFTH CLAIM FOR RELIEF

INFRINGEMENT OF UNITED STATES PATENT NO. 6,258,569

64. In response to paragraph 64 of the FAC, Biosearch realleges and incorporates by reference the answers stated in paragraphs 1-63 above.

65. Biosearch admits that the face of the '569 patent indicates it issued on July 10, 2001, and that Plaintiffs attached what purports to be a true and correct copy of this patent as Exhibit E to the FAC. Biosearch is without knowledge or information sufficient to form a belief as to the remainder of the allegations contained in paragraph 65 and, on that basis, denies said allegations.

66. Biosearch denies each and every allegation of paragraph 66.

67. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 67 and, on that basis, denies said allegations.

68. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 68 and, on that basis, denies said allegations.

69. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 69 and, on that basis, denies said allegations.

70. Biosearch denies each and every allegation of paragraph 70.

71. Biosearch denies the allegations contained in paragraph 71 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 71 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

72. Biosearch denies the allegations contained in paragraph 72 to the extent they pertain to Biosearch. Biosearch is without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 72 to the extent they pertain to other Defendants and, on that basis, denies said allegations.

RESPONSE TO PLAINTIFFS' JURY DEMAND

73. Biosearch states that Plaintiffs' jury demand does not require a response.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

74. Biosearch denies that Plaintiffs are entitled to the relief sought, or any other relief.

AFFIRMATIVE DEFENSES

Further answering the FAC, Biosearch asserts the following defenses. Biosearch reserves the right to amend its Answer with additional defenses as further information is determined.

FIRST DEFENSE

(Non-infringement of the Asserted Patents)

75. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

76. Biosearch has not infringed, contributed to the infringement of, or induced the infringement of any valid claim of the '848, '591, '930, '787, or '569 patents, and is not liable for infringement thereof.

SECOND DEFENSE

(Invalidity of the Asserted Patents)

77. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

78. One or more claims of each of the '848, '591, '930, '787, and '569 patents are invalid for failing to comply with the provisions of the Patent Laws of the United States, including without limitation 35 U.S.C. §§ 101, 102, 103 and/or 112, and Plaintiffs' claims for relief are therefore barred.

THIRD DEFENSE

(Lack of Standing to Sue)

79. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

80. Upon information and belief, Plaintiffs lack standing to sue because neither holds sufficient rights to one or more of the '848, '591, '930, '787, and/or '569 patents.

FOURTH DEFENSE

(Prosecution History Estoppel)

81. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

82. To the extent that Plaintiffs attempt to assert infringement under the doctrine of

equivalents, Biosearch believes that arguments and amendments contained in the prosecution history of the '848, '591, '930, '787, and/or '569 patents will estop or bar any claims for alleged infringement.

FIFTH DEFENSE

(Unclean Hands)

83. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

84. Plaintiffs' claims for alleged infringement are barred or limited by the doctrine of unclean hands and other equitable doctrines.

SIXTH DEFENSE

(Laches)

85. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

86. Plaintiffs' FAC is barred, in whole or in part, under the doctrine of laches. By way of example, and without limitation, Biosearch alleges, on information and belief, that Plaintiffs' claims under the '848, '591, '930, '787, and '569 patents are barred by the doctrine of laches because (1) Plaintiffs knew of Biosearch's allegedly infringing actions since at least June 1998, (2) Plaintiffs inexcusably failed to pursue their infringement claims in a timely and diligent manner from the time it became aware it had claims against Biosearch, and (3) Biosearch has been materially prejudiced by Plaintiffs' inexcusable lack of diligence.

SEVENTH DEFENSE

(Inequitable Conduct Based on Prosecuting Attorney's Intentional Mischaracterization of the Heller Reference)

87. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

88. The '591 patent is unenforceable for inequitable conduct during its prosecution.

89. David J. Weitz was one of the attorneys involved with the prosecution of the '591 patent application and acted on behalf of Dr. Livak and the other named inventors.

90. As one of the prosecuting attorneys, Mr. Weitz had a duty of candor and good faith in dealing with the PTO during the prosecution of the '591 patent application. 37 C.F.R. §

1.56(a).

91. During the prosecution of the '591 patent application, in an Office Action dated July 22, 1996 (the "Office Action"), the examiner rejected numerous claims as anticipated by European Patent Application 0 229 943, "Fluorescent stokes shift probes for polynucleotide hybridization assays," filed December 1, 1986 (the "Heller Reference"). The examiner characterized the Heller Reference as disclosing a fluorescent probe used in polynucleotide hybridization assays that comprises donor and acceptor fluorophores, in which maximum acceptor fluorophore emission is observed when the probe hybridizes to its target sequence.

92. In response to the Office Action, Mr. Weitz signed and submitted an Amendment dated October 22, 1996 (the "Amendment"). In the Amendment, Mr. Weitz argued that, upon introduction of the "at least a factor of 6" limitation into the independent claims, the rejected claims were no longer anticipated by the Heller Reference because the reference "does not teach a probe which when hybridized to a target polynucleotide has a fluorescence intensity which is at least a factor of 6 greater than when the oligonucleotide probe is not hybridized to the target polynucleotide" Amendment at 13. To prove this point, Mr. Weitz relied on data contained in Table 3 of the '848 patent, which purportedly showed that an increase in reporter fluorescence intensity greater than 6-fold is achieved upon probe hybridization. Amendment at 11. Mr. Weitz claimed that, in contrast, the data contained in Table A of the Heller Reference "teaches that a probe with a separation of 12 nucleotides has an unhybridized / hybridized fluorescence emission ratio of only 1.3 (17/13)." *Id.*

93. Mr. Weitz' characterization of the Heller Reference is false and misleading because the level of increase in reporter fluorescence intensity upon hybridization is not actually disclosed in the Heller Reference. Specifically, the Heller Reference describes the properties of double-labeled probes in terms of "Energy Transfer," which is calculated as (Quencher emission when reporter excited) / (Quencher emission when quencher excited) x 100. In contrast, the probes in Table 3 of the '848 patent are characterized in terms of "RQ Ratio," which is calculated as (Reporter emission when reporter excited) / (Quencher emission when reporter

excited). The 6-fold or greater increase in reporter fluorescence intensity upon hybridization is calculated based on RQ Ratios according to the '848 patent. RQ Ratios of the same type as those disclosed in the '848 patent cannot be determined for the probes based on Table A or any other data reported in the Heller Reference because no raw data are provided therein to support the calculation. In other words, the level of increase in reporter fluorescence intensity cannot be calculated based on any of the data disclosed in the Heller Reference.

94. Mr. Weitz' misrepresentation of the Heller Reference persuaded the examiner to withdraw the anticipation rejection of numerous claims over the Heller Reference. As such, his misleading arguments directly relate to the patentability of the claims in the '591 patent.

95. On information and belief, Mr. Weitz intentionally misrepresented the Heller Reference with the intention to mislead or deceive the PTO.

96. Due to the inequitable conduct committed during the prosecution of the '591 patent by Mr. Weitz, any other patents with an immediate and necessary relationship to this patent, including but not limited to any patents in the same family, are further unenforceable by Plaintiffs.

EIGHTH DEFENSE

(Inequitable Conduct Based on Named Inventors' Intentional Nondisclosure and Misrepresentation of Material Information)

97. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

98. The '848, '591, '930, '787, and '569 patents are unenforceable for inequitable conduct during their prosecution.

99. On information and belief, Kenneth J. Livak ("Dr. Livak") and/or one or more of the other named inventors, Susan J. Flood, Jeffrey Marmaro, and Khairuzzaman Bashar Mullah (collectively or individually "Dr. Livak et al.") were leading investigators in the field of dual-labeled probes who were named as inventors on the '848, '591, '930, '787, and/or '569 patents. As explained below, however, Dr. Livak et al. were aware of information material to the patentability of the claims of the '848, '591, '930, '787, and '569 patents, but withheld that

information from the U.S. Patent and Trademark Office (the “PTO”) with intent to deceive the PTO.

100. As named inventors, Dr. Livak et al. had a “duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability” of any of the claims in the applications for the ‘848, ‘591, ‘930, ‘787, and ‘569 patents. 37 C.F.R. § 1.56. This “duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned.” *Id.* Dr. Livak et al. explicitly acknowledged this disclosure duty in declarations filed during the prosecution of the applications for the ‘848, ‘591, ‘930, ‘787, and/or ‘569 patents. As explained below, Dr. Livak et al. breached this duty by not disclosing information they knew were material to the patentability of the ‘848, ‘591, ‘930, ‘787, and/or ‘569 patents.

101. The claims of the ‘848, ‘591, ‘930, ‘787, and ‘569 patents are all directed at dual-labeled oligonucleotide probes incorporating a quencher and fluorophore reporter and methods of using the same. Indeed, according to Plaintiffs’ own allegations in the FAC, the claims of these patents read on dual-labeled oligonucleotide probes incorporating a quencher and fluorophore reporter and methods of using the same.

102. On information and belief, throughout the prosecution of the ‘848, ‘591, ‘930, ‘787, and ‘569 patents, Dr. Livak et al. were aware of the existence of prior art that disclosed dual-labeled oligonucleotide probes incorporating a quencher and fluorophore reporter for use as a fluorescence resonance energy transfer (FRET) probes. Specifically, Dr. Livak et al. were aware of the reference Sudhir Agrawal and Paul C. Zamecnik, “Site Specific Functionalization of Oligonucleotides for Attaching Two Different Reporter Groups,” *Nucleic Acids Research*, vol. 18, no. 18, 5419-5423 (1990) (hereinafter “Agrawal Reference”) since at least November 16, 1994, because the Agrawal Reference is mentioned in the Specification section of the application that led to the ‘848 patent (filed Nov. 16, 1994).

103. The Agrawal Reference, a publication pre-dating the filing date of the ‘848 patent

application by nearly 4 years, was material to patentability of the claims of the '848, '591, '930, '787, and '569 patents because it discloses and teaches how to make dual-labeled oligonucleotide probes incorporating a quencher and fluorophore reporter. Throughout the prosecution of these patents, Dr. Livak et al. knew or should have known that the Agrawal Reference was directly relevant to the claims of these patents because it is mentioned in the Specification sections for each of them. Dr. Livak et al. also knew that the Agrawal Reference was material to claims directed to dual-labeled oligonucleotide probes incorporating a quencher and fluorophore reporter because this reference was cited on an IDS submitted during the prosecution of the '569 patent. On information and belief, Dr. Livak et al. also knew or should have known of the Agrawal Reference because it is a scientific publication that relates to dual-labeled probes, a field in which they had been active and for which they regularly reviewed scientific publications; as such, Dr. Livak et al. would have reviewed the Agrawal Reference at or around the time it was published. Despite knowing of the materiality of the Agrawal Reference to the claims of all the patents, Dr. Livak et al. nonetheless misled or deceived the PTO as to the materiality and substance of the Agrawal Reference in at least the following ways.

104. *First*, despite knowing about the Agrawal Reference since at least November 1994, Dr. Livak et al. failed to identify the Agrawal Reference on any Information Disclosure Statement ("IDS") submitted during the prosecution of the prosecution of the '848, '591, '930, and '787 patents, a period spanning nearly 6 years. Only in June 2000, during the prosecution of the '569 patent, did Dr. Livak et al. submit an IDS identifying the Agrawal Reference. At that point, however, *the '848, '591, '930, and '787 patents had already issued.*

105. Even though the Agrawal Reference was mentioned in the Specification sections of these patents, Dr. Livak et al. had a duty to list the Agrawal Reference on an IDS starting with the prosecution of the '848 patent in November 1994. According to PTO procedure, "[e]ach [IDS] must include a list of all patents, publications or other information submitted for consideration by the [PTO]." Manual of Patent Examining Procedures § 609(A)(1) (5th ed. rev. 14 Nov. 1992). "To comply with this requirement, the list may not be incorporated into the

specification but must be submitted in a separate paper.” *Id.*

106. As detailed above, Dr. Livak et al. breached this duty by not listing the Agrawal Reference on an IDS submitted in connection with the prosecution of the applications that led to the ‘848, ‘591, ‘930, and ‘787 patents, even though disclosure of this reference would have had a significant and material impact on the patentability of the claims in these applications.

107. *Second*, on information and belief, Dr. Livak et al. never submitted a copy of the Agrawal Reference to the PTO at any point over the 6-year-long prosecution of the ‘848, ‘591, ‘930, and ‘787 patents, which may have allowed the examiner to consider the materiality of the reference for one or more of these patents.

108. *Third*, Dr. Livak et al. mischaracterized the Agrawal Reference in the Specification section in each of the patents. In each of the patents’ Specification section, Dr. Livak et al. state that “[o]ligonucleotide probes of the invention can be synthesized by a number of approaches” and cite the Agrawal Reference as teaching one of these approaches. ‘848 at 5:9-12; ‘591 at 10:16-19.; ‘930 at 10:51-54; ‘787 at 10:54-57; ‘569 at 10:46-50. This characterizes the Agrawal Reference as merely teaching *an approach* that can be used to synthesize the types of probes claimed in the patents. Dr. Livak et al. failed to explain in the Specification or elsewhere that the Agrawal Reference not only teaches a synthesis approach *but also* discloses types and examples of probes resulting from such synthesis. Dr. Livak et al. further failed to explain anywhere that the probes disclosed in the Agrawal Reference are the *exact same type* as those covered by the composition and method claims of the ‘848, ‘591, ‘930, and ‘787 patents—*i.e.*, dual-labeled oligonucleotide probes incorporating a quencher and fluorophore reporter.

109. On information and belief, Dr. Livak et al. misled or deceived the PTO in at least the aforementioned ways with the intention to mislead or deceive the PTO as to the materiality the Agrawal Reference to the claims of the ‘848, ‘591, ‘930, ‘787, and/or ‘569 patents.

110. Due to the inequitable conduct committed during the prosecution of the ‘848, ‘591, ‘930, ‘787, and/or ‘569, patents by Dr. Livak et al., any other patents with an immediate and necessary relationship to these patents, including but not limited to any patents in the same

family, such as the '569 patent, are further unenforceable by Plaintiffs.

NINTH DEFENSE

(Unavailability of Relief)

111. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

112. Plaintiffs have failed to plead and meet the requirements of 35 U.S.C. § 271(b) and (c) and are not entitled to any alleged damages prior to providing any actual notice to Biosearch of the '848, '591, '930, '787, or '569 patents.

TENTH DEFENSE

(Adequate Remedy at Law)

113. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

114. Plaintiffs' claims for injunctive relief are barred in light of the fact that Plaintiffs have an adequate remedy at law.

ELEVENTH DEFENSE

(Unavailability of Enhanced Damages)

115. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

116. Plaintiffs have failed to plead and meet the requirements of 35 U.S.C. §§ 284 and 285 for increased damages and attorneys' fees and are not entitled to any alleged damages prior to providing any actual notice to Biosearch of the '848, '591, '930, '787, or '569 patents.

TWELFTH DEFENSE

(Failure to Mark)

117. Biosearch incorporates by reference paragraphs 1 through 74 of its Answer.

118. Plaintiffs' claims for damages are barred or limited due to failure by Plaintiffs to allege compliance with, and failure to comply with, the requirements of 35 U.S.C. § 287.

PRAYER FOR RELIEF

WHEREFORE, Biosearch respectfully prays for the entry of judgment as follows:

A. Dismissing with prejudice any and all claims of Plaintiffs' FAC and ordering that Plaintiffs take nothing as a result of the FAC;

- B. Judging the '848, '591, '930, '787, and '569 patents and their claims invalid;
- C. Judging the '848, '591, '930, '787, and '569 patents and their claims unenforceable;
- D. Judging that Biosearch has not and does not infringe, directly or indirectly, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '848, '591, '930, '787, and '569 patents
- E. That Plaintiffs be denied any remedies available under 35 U.S.C. § 284;
- F. That the Court denies Plaintiffs any injunctive relief;
- G. That the Court denies Plaintiffs any other relief as to the First through Fifth Claims for Relief;
- H. Finding that this is an exceptional case and awarding Biosearch its attorneys' fees as the prevailing party pursuant to 35 U.S.C. § 285;
- I. That the Court award Biosearch its costs of suit; and
- J. That the Court award such further relief as deemed just and proper.

BIOSEARCH'S COUNTERCLAIMS

119. Counterclaimant Biosearch hereby submits these counterclaims pursuant to Federal Rule of Civil Procedure 13 and incorporates by reference paragraphs 1 through 118 of its Answer.

120. There is an actual controversy between Biosearch and Plaintiffs regarding non-infringement, validity, and/or unenforceability of the '848, '591, '930, '787, and '569 patents because Plaintiffs have asserted that Biosearch infringes the '848, '591, '930, '787, and '569 patents.

121. This is an action for declaratory relief brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338, and 1367.

122. Biosearch is a California corporation with its principal place of business at 81 Digital Drive, Novato, California 94949.

123. Upon information and belief, Plaintiff Life Technologies is a Delaware corporation with a principal place of business at 5791 Van Allen Way, Carlsbad, California 92008.

124. Upon information and belief, Plaintiff Applied Biosystems, LLC is a Delaware limited liability corporation with a principal place of business at 850 Lincoln Centre Drive, Foster City, California 94404.

125. This Court has personal jurisdiction over Plaintiffs at least because Plaintiffs submitted themselves to this Court's personal jurisdiction by suing Biosearch and the other Defendants in this Court.

126. Venue for these counterclaims is proper in this Court under 28 U.S.C. § 1391 and under the doctrine of pendant venue because these counterclaims are closely related to the claims set forth in the FAC.

FIRST COUNTERCLAIM

(Invalidity)

127. Biosearch incorporates by reference paragraphs 119-126 of its Answer and Counterclaims.

128. The claims of the '848, '591, '930, '787, and '569 patents are invalid for failure to meet the requirements of one or more sections of 35 U.S.C. §§ 101 *et seq.*

129. The claims of the '848, '591, '930, '787, and '569 patents are invalid for failing to comply with the provisions of the Patent Laws of the United States, including without limitation 35 U.S.C. §§ 101, 102, 103 and/or 112.

SECOND COUNTERCLAIM

(Non-infringement)

130. Biosearch incorporates by reference paragraphs 119-126 of its Answer and Counterclaims.

131. Biosearch has not infringed and is not infringing, either directly or indirectly, any valid and enforceable claim of any of the '848, '591, '930, '787, and '569 patents.

THIRD COUNTERCLAIM

(Unenforceability)

132. Biosearch incorporates by reference paragraphs 119-126 of its Answer and Counterclaims.

133. The '848, '591, '930, '787, and '569 patents are unenforceable for inequitable conduct during their prosecution. Biosearch incorporates herein by reference, as if fully set forth, the allegations of paragraphs 87-110, inclusive, of Biosearch's Answer above.

PRAYER FOR RELIEF

WHEREFORE, Biosearch respectfully prays for the entry of judgment as follows:

- A. Judging the '848, '591, '930, '787, and '569 patents and their claims invalid;
- B. Judging the '848, '591, '930, '787, and '569 patents and their claims unenforceable;
- C. Judging that Biosearch has not and does not infringe, directly or indirectly, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '848, '591, '930, '787, and '569 patents.
- D. Finding that this is an exceptional case and awarding Biosearch its reasonable costs of suit and attorneys' fees pursuant to 35 U.S.C. § 285; and
- E. That the Court award such further relief as deemed just and proper.

DEMAND FOR JURY TRIAL

Biosearch hereby demands trial by jury on all issues.

Dated: January 5, 2010

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

/s/ Winstol D. Carter, Jr.

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**Attorneys for Defendant Biosearch Technologies,
Inc.**

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document has been served on all counsel of record via the Court's Case Management/Electronic Case Filing system on January 5, 2010.

/s/ Winstol D. Carter, Jr.

Winstol D. Carter, Jr.